Guidance on

Good Manufacturing Practices for food contact plastic materials and articles

Asociación Valenciana de Empresarios de Plásticos

GENERALITAT VALENCIANA
CONSELLERIA DE SANITAT

PLA DE SEGURETAT ALIMENTÀRIA DE LA COMUNITAT VALENCIANA

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EVALUATION CERTIFICATE

This **Guidance on Good Manufacturing Practices for food contact plastic materials and articles**, developed by AVEP (Valencian Plastic Industries Association) in association with AIMPLAS-Technological Institute of Plastics, has been evaluated based on the requirements set out in Regulation (EC) No 1935/2004 of the European Parliament (EC) of 27 October 2004, on materials and articles intended to come into contact with food, as well as those set out in Article 5-Quality assurance system, of Commission Regulation (EC) No 2023/2006 of 22 December 2006, on good manufacturing practice for materials and articles intended to come into contact with food, specifically for the plastic materials and articles covered by Commission Regulation (EC) No 10/2011. The result of said evaluation is its:

APPROVAL

DIRECTOR GENERAL OF RESEARCH AND PUBLIC HEALTH

GENERALITAT VALENCIANA CONSELLERIA DE SANITAT

Manuel Escolano Puig

Greater diversification in food industry implies a parallel development in the packaging sector, even including the development of active materials able to interact with packaged product. This situation has led to new European and national regulations, which companies are striving to adapt to.

Specifically, the inclusion of Regulation 2023/2006, on good manufacturing practices for materials and articles intended to come into contact with food, into the national legislative, in particular with reference to the obligation of companies within the sector to implement quality control systems, has meant that the General Board of Research and Public Health has decided to develop a manual to help companies fulfil the legal obligations.

The 'Guidance on Good Manufacturing Practices for food contact plastic materials and articles' is aimed at industries involved in the processing, distribution and importation of plastic materials and articles intended to come into contact with food, and its main objective is to guarantee that quality control systems are applied in an effective way in order to prevent possible health problems due to inappropriate manufacturing practices.

This guidance document has been developed in association with AVEP (Valencian Plastic Industries Association) and with technical advice from AIMPLAS-Technological Institute of Plastics. This wide participation in its development gives an idea of the commitment of the sector to protecting consumer health.

In addition to this, the document will serve as a reference, adding uniformity to official inspections within the Valencian Community, and at the same time it will establish the criteria required for companies to comply with legislation.

I am grateful for the effort and dedication that the authors and collaborators have shown in the production of this guidance document, and I encourage the companies to strengthen their resolve to guarantee that their manufactured products do not transfer any substances to foodstuffs which may be detrimental to consumers' health.

Manuel Escolano Puig

Director General of Research and Public Health

AVEP (Valencian Plastic Industries Association) has always been involved in activities aimed at encouraging companies to improve and adapt their production processes to be more environmental and health-friendly. At present, this focus is not only appropiate but also highly necessary.

The development of this Guidance on Good Manufacturing Practices for food contact plastic materials and articles, will lead the way for the implementation of self-control and continual improvement in manufacturing and handling processes in the industry. Moreover, it will be a reference document for the external inspections which companies must undergo due to their activity, establishing uniform criteria for these inspections.

This guidance document can also help us to improve quality of our products. In an ever more demanding market, we can only be competitive if we have a quality product adapted to health regulations.

We thank the General Board of Research and Public Health for its continuous support over our concerns. We sincerely believe that these initiatives are for the benefit of all.

We would like to congratulate all the collaborators in the development of this document for their hard work and professionalism, related to highly interesting matters for plastics sector.

We are sure that this Guidance on Good Manufacturing Practices for food contact plastic materials and articles will be extremely useful for companies in food packaging sector identified within the scope of the document. It will surely help them to improve their systems with regard to food safety, which, eventually, is in the interest of all citizens.

Salvador Benedito Gómez

President of AVEP

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1. Introduction

Converters of plastic materials and articles intended to come into contact with food are seen more and more as companies closely tied to food sector and, therefore, within the sphere of requirements of said sector. Food companies which use plastic materials and articles are demanding, due to legal requirements, and, based on their own initiative, greater and greater hygiene and safety measures.

Moreover, with recent adoption of new European regulations and legal requirements, implementation of quality and hygiene systems able to make food contact materials safer has been deemed necessary. Specifically, Regulation 2023/2006 sets out rules concerning Good Manufacturing Practices for groups of materials and articles intended to come into contact with food. This Regulation is binding since 1st August 2008.

Due to the above, companies must maintain an effective control over processes and substances used in manufacturing of plastic materials and articles intended to come into contact with food, in order to control migration levels with the aim of avoiding health problems.

At present there are many guidance documents on good manufacturing practices (GMPs) within the food industry sector. They mainly provide information about the application of Regulation (EC) Nº 852/2004, that is the reference framework in application of hygiene practices in food industry. However, when considering food contact plastic materials and articles, existing guidance documents are limited to merely establishing broad guidelines. They do not focus on details concerning how to implement an appropriate system taking into account the manufacturing process and the level of risk. This guidance document aims to be adaptable to different types of companies involved in the manufacturing of food contact plastic materials and articles, and to be a reference framework to help companies complying with current legislation.

This document is based on principles fully compatible with:

- Current legislation.
- General safety and hygiene guidelines.
- Voluntary certification systems.

2. Objective

The main objective of this guidance document is to facilitate converters, storage and distribution companies and importers of plastic materials and articles intended to come into contact with food the implementation of requirements set out in Regulation (EC) No 2023/2006 on good manufacturing practices for groups of materials and articles intended to come into direct or indirect contact with food.

3. Scope

The guidance document is addressed to industries involved in the processing, distribution and importation of:

a) Materials and articles and parts thereof consisting exclusively of plastics.

b) Plastic multi-layer materials and articles held together by adhesives or by other means.

c) Materials and articles referred to in points a) or b) that are printed and/or covered by a coating.

d) Plastic layers or plastic coatings, forming gaskets in caps and closures, that together with those caps and closures compose a set of two or more layers of different types of materials.

e) Plastic layers in multi-material multi-layer materials and articles.

Figure 1 shows the manufacturing stages in which this guidance document is applicable.

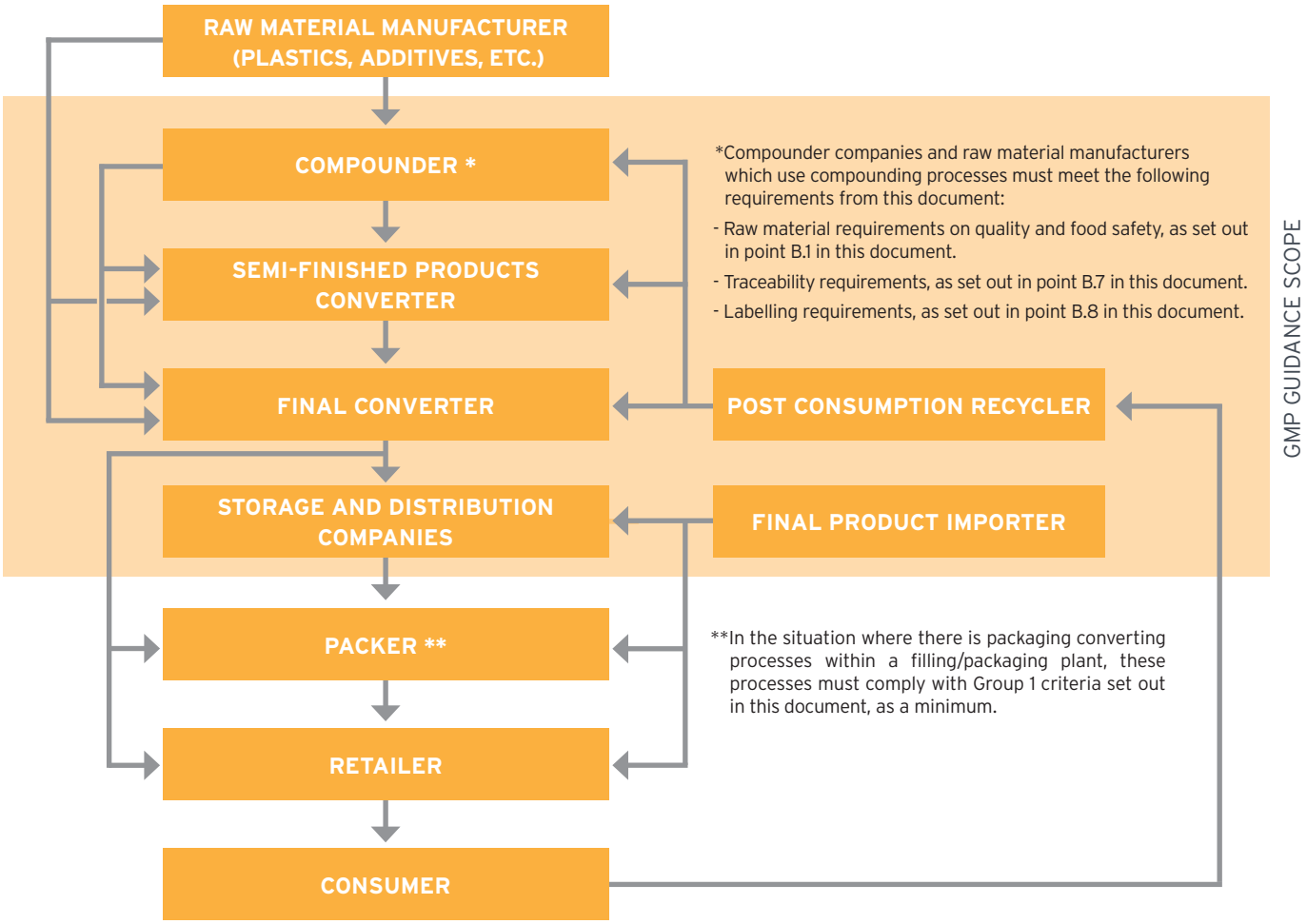


Figure 1: Production flow in the Value Chain of Food Packaging.

4. Definitions

- **Additive:** Any substance added to polymers during synthesis, production or processing, in order to stabilize them, make those processes easy to carry out and/ or modify the final properties of finished product.
- **Biological contamination:** All types of contamination coming from a biological source which could be harmful toward the final product.
- **Chemical contamination:** All types of contamination coming from a chemical source which could be harmful toward the final product.
- **Compounder:** A company dedicated to the formulation of materials through the compounding process (mixing).
- **Compounding:** The addition of any other type of material (organic or inorganic) to a polymer in order to modify the properties of the initial polymer.
- **Declaration of Compliance:** A written declaration which certifies that the materials and articles comply with the regulations applicable to them.
- **Direct contact:** When the plastic material or article is in direct contact with the foodstuffs.
- **Dual use additives:** Any substance that can be used as an additive in both plastic materials and foodstuffs.
- **Functional barrier:** A barrier made up of one or various layers which guarantees that substances behind the barrier cannot migrate into the foodstuffs.
- **Good manufacturing practices:** Those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof.
- **Indirect contact:** When the plastic material or article is not in direct contact with the foodstuffs.
- **Migration:** The transfer of components (monomers and oligomers, additives, etc.) from the structure of the packaging to the foodstuff or product in contact with the plastic material.
    - **Overall migration:** The total amount of substances which transfer from the material or article into the foodstuff, regardless of the source of the migrating substance.
    - **Specific migration:** The amount of a defined substance which transfers from the material or article into the foodstuff.
- **Multi-layer structure:** A material or article composed of two or more layers of different types of materials, being at least one of them a plastic layer.
- **Organoleptic or sensory analysis:** Analysis of foodstuffs or other materials, using the senses.

- **Packaging:** Any container intended to contain foodstuffs and whose specific goal is to protect these foodstuffs from deterioration, contamination or adulteration.

- **Packing:** This covers the main types of containers which are used to handle, transport or store the product throughout the logistical chain.

- **Plastic materials or articles with several layers (multi-layer structures):** A plastic material or article composed of two or more layers of material which are held together by adhesives or any other method.

- **Plastic raw material:** A polymer to which additives or other substances can be added and which acts as the main structural component of end materials or articles. As far as this guidance document is concerned, two types of raw material can be distinguished:

    - **Plastic in the form of powder, pellets or flakes:** This refers to the plastic material in the form of powder, pellets or flakes prior to its processing. This also refers to raw material when talking about adhesives, inks and/ or varnishes. When the text is referred to these cases, it will be clearly specified.

    - **Semi-finished product:** This refers to material which has already been processed and which is used to manufacture final articles in which processes of handling or final finishing can be applied, such as lamination, printing, winding, cutting, assembling, etc.

- **Physical contamination:** The introduction of a physical contaminant in the material or article intended to be in contact with foodstuffs, which could suppose a risk for the consumer or user.

- **Quality assurance system:** The total sum of the organised and documented arrangements made with the purpose of ensuring that materials and articles are of the quality required to ensure conformity with the rules applicable to them and the quality standards necessary for their intended use.

- **Quality control system:** The systematic application of measures established within the quality assurance system that ensure compliance of starting materials and intermediate and finished materials and articles with the specification determined in the quality assurance system.

- **Quality protocol:** A voluntary document which defines some guidelines for the companies in order to meet some requirements, so as to establish practices which assure the quality of the final products.

- **Recycled plastic material:** Material which has been recycled by means of a process according to Regulation 282/2008.

- **Technical datasheet:** A document which includes technical properties of an article or material, that can also be critical for its end use.

- **Traceability:** The ability to trace and follow a material or article throughout all the stages of production, processing and distribution.

5. Legal framework

- **Regulation (EC) No 1935/2004** of the European Parliament and of the Council, of 27 October 2004, on materials and articles intended to come into contact with food.
- **Commission Regulation (EC) No 2023/2006**, of 22 December 2006, on good manufacturing practice for materials and articles intended to come into contact with food.
- **Commission Regulation (EC) No 282/2008**, of 27 March 2008, on recycled plastic materials and articles intended to come into contact with foods.
- **Spanish Royal Decree 866/2008**, of 23 May 2008, which approves a list of substances permitted in the manufacture of plastic materials and articles intended to come into contact with foods and which regulates specific testing conditions.

  Repealed, except for the part stipulated for migration testing and food simulants, which will remain in force until the dates stated in Articles 22 and 23 of Regulation 10/2011.
- **Commission Regulation (EC) No 450/2009**, of 29 May 2009, on active and intelligent materials and articles intended to come into contact with food.
- **Commission Regulation (EC) No 10/2011**, of 14 January 2011, on plastic materials and articles intended to come into contact with food.
- **Spanish Royal Decree 191/2011**, of 18 February 2011, concerning the general health registry of food companies and foodstuffs.
- **Spanish Royal Decree 846/2011**, of 17 June 2011, which establishes the conditions that raw materials based on recycled polymeric materials must fulfil in order to be used in materials and articles intended to come into contact with foodstuffs (BOE 11 July 2011).
- **Spanish Royal Decree 847/2011**, which establishes the positive list of substances permitted to manufacture polymeric materials intended to come into contact with foodstuffs.

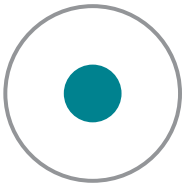
  It repeals Resolution dated 4 November 1982, except for waxes and supports for polymerization.

6. Plastics industry: Groups based on risk

6.1 GENERAL CLASIFICATION

Based on the level of risk, three groups of final products have been defined related to types of articles and their end uses.

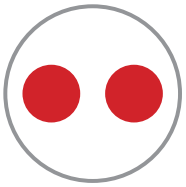
The three risk levels are set out below, from greatest to least. Some examples are also included:



Group 1. Plastic materials and articles intended to come into direct contact with food without protection barrier.

Plastic materials and articles intended to come into direct contact with food and with a high risk of contamination such as:

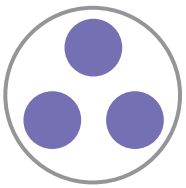
- Bottles for liquids and sauces.
- Trays for meat, processed meat, sliced meats, cheeses, ready-to-eat fresh and prepared food, etc.
- Films for pasta, vegetables, frozen foods, ready-to-eat fresh and prepared food, etc.



Group 2. Plastic materials and articles intended to come into direct contact with food with protection barrier.

Plastic materials and articles intended to come into direct contact with food, where the food is protected against possible contaminants derived from the packaging, or the food contains physical contamination higher than the packaging can add, or articles which specify a series of measures before their use, for example:

- Trays or films for food which has its own protective layer, such as fruit with skin or cheese with rind, etc.
- Film and trays for whole fruit and vegetables, etc.
- Mesh bags for potatoes or onions, etc.
- Household articles, lunch boxes, kitchenware, and other reusable articles.



Group 3. Plastic materials and articles intended to come into indirect contact, or cases of direct contact in special situations which due to their end use do not require special hygiene measures.

Plastic materials and articles intended to come into indirect contact with food; or the ones which, when used, have any possibility of direct contact; and other special applications of direct contact that due to the process itself, do not require restrictive hygiene measures. Some examples are the following:

- Containers such as plastic boxes or baskets for agriculture, which due to their use are intended to come into direct contact with the ground.
- Packing material, pallets, boxes, external packaging film, plastic shopping bags used to carry food, etc.

Group 1 equates to plastic materials and articles of highest risk, and therefore companies in this group must adhere to all the points raised in this guidance document. For Group 2, the requirements are reduced. For Group 3, the minimum measures demanded for the manufactured product are considered sufficient.

When a company is dedicated to the manufacture of articles belonging to different groups, then it should be assimilated to the group which implies the highest risk.

The guidance document also considers measures for storage and distribution companies and importers and import companies not carrying out any form of processing or handling of the plastic materials or articles.

Companies in which there are stages of packaging handling, for example cutting reels, assembly of lunch boxes, silk screen printing of primary packaging, packing of unit containers, etc., will not be considered as warehouses, and they should be assimilated to one of the three groups mentioned above based on the associated risk.

Figure 2 establishes a decision tree for classifying companies based on their level of risk.

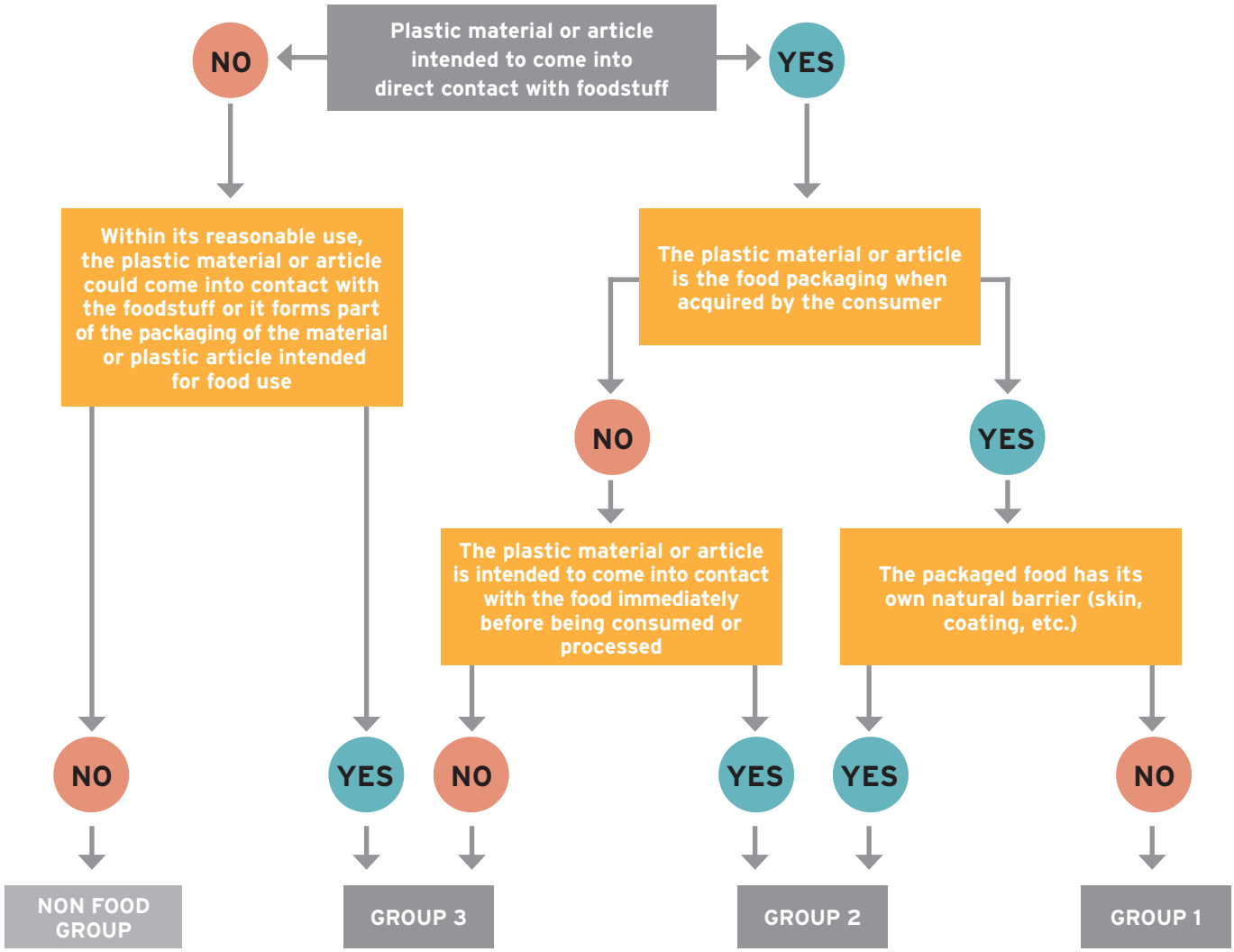


Figure 2. Decision tree to establish the risk group of a company.

7. Requirements for converters of plastic materials intended to come into contact with foodstuffs

Figure 3 shows a diagram which describes, for a packaging manufacturer, the typical processes required to develop a quality system able to assure good manufacturing practices.

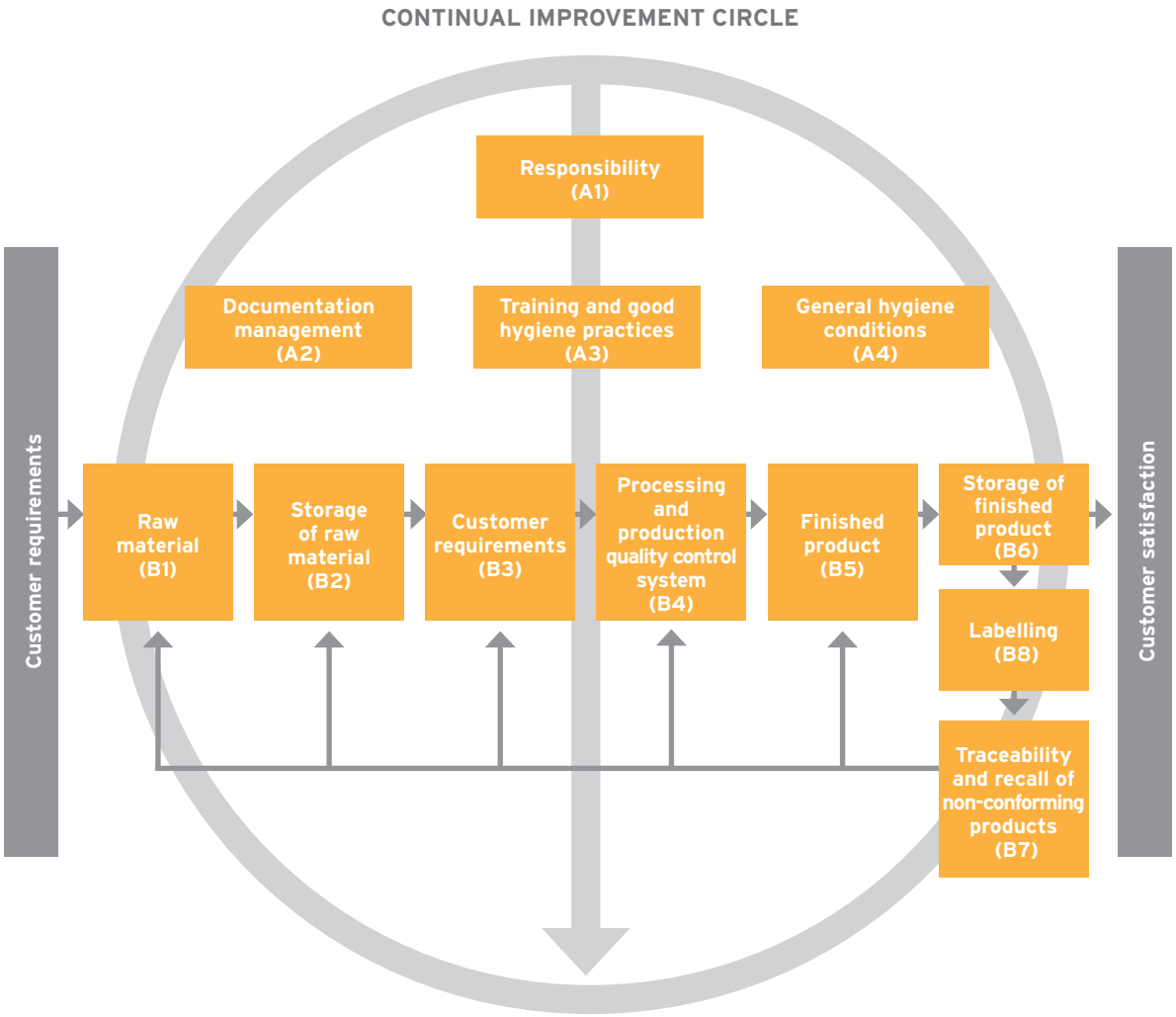


Figure 3. Main requirements for a plastic materials and articles manufacturer.

A. GENERAL SYSTEM REQUIREMENTS

A.1. RESPONSIBILITY

An organisation chart shall be made available along with a description of the roles and responsibilities of all members of staff involved in Good Manufacturing Practices.

The companies shall have a system which guarantees updating, diffusion and implementation of legislation. A person shall be designated to head up and ensure the application of food safety regulations (Head of Application of Food Safety Regulations, HAFSR).

Final responsibility for the system shall rest with Senior Management of the company.

A.2. DOCUMENTATION CONTROL

Groups 1, 2 and 3, storage and distribution companies and importers.

The companies must have a documentation control procedure. The documents must be stored for a minimum of five years. An example of a procedure can be found in Annex 1.

The mandatory documents and records are set out in the table below:

Requirement	Procedures, plans, rules and main documents	Support documents	Records
Responsibilities (A.1)	Organisation chart including roles and responsibilities of members of staff. The person responsible for maintaining the quality system (HAFSR) must be clearly identified		
Documentation Control (A.2)	Documentation control procedure		Record of Documentation revision
			Record of Documentation distribution
			Documentation form acknowledgement
Training and good hygiene practices (A.3)	Hygiene policy		Record of hygiene policy reading
	Hygiene rules		Record of hygiene rules reading
	Training plan	Training certificates	Record of attendance and evaluation of training activities

Requirement	Procedures, plans, rules and main documents	Support documents	Records
General hygiene conditions (A.4)			
Facilities and equipment hygiene (A.4.1)	Cleaning plan		Cleaning record
			Purging record (food contact material – non-food contact material)
Water control (A.4.2)	Water quality plan	Potable water supply bill	Record of water control parameters
		Copy of water quality analysis report carried out by water distribution system operator.	
		Report containing parameters included in RD 140/2003	
Maintenance (A.4.3)	Preventive maintenance plan	Invoices related to external maintenance activities and warranty document if it exists	Record of hygiene rules reading (non-staff members)
			Equipment maintenance record
	Calibration plan for measuring equipments critical for food safety		Calibration record
Pest control (A.4.4)	Pest control plan	Pest control report	Record of pest surveillance
Waste management (A.4.5)			
Raw material (B.1)	Raw material control plan	Technical datasheets	Visual inspection record of raw material conditions when received
		Declaration of compliance	
Raw material storage (B.2)			
Customer requirements (B.3)		Customer requirements	

Requirement	Procedures, plans, rules and main documents	Support documents	Records
Processing and production (B.4)	Processing parameters		Monitoring record for specified parameters
			Non-conformity records
			Record of corrective measures
Finished product (B.5)	Quality parameters	Laboratory reports	Record of quality checks carried out internally
	Food safety parameters	Laboratory reports	Record of process verification
		Declaration of Compliance of finished product	Record of corrective measures
Storage of finished product (B.6)			
Traceability (B.7)	Traceability procedure		Traceability exercise record
Labelling (B.8)			
Continual improvement (9)	Example of continual improvement		Customer complaints/ claims record Record of incidents detected during the manufacturing process Record of products not meeting the quality standard, pointing out which parameter or parameters it does not meet Record of customer level of satisfaction with regard to the product received. Record of official test control communications Record of official control tests results

A.3. TRAINING AND GOOD HYGIENE PRACTICES

The company shall have a hygiene policy and staff hygiene rules aligned with the objectives of this Guidance. An example template of a hygiene policy can be found in Annex II.

The company shall commit to disseminate the policy and hygiene rules to the members of staff who are obliged to fulfil them.

The company shall also have a training plan, along with attendance and evaluation records for the training activities.

The minimum requirements which must be covered in training and hygiene policy according to Good Manufacturing Practices are shown below:

Requirement	Group
• New members of staff must be trained and informed about general hygiene concept, good manufacturing practices and hygiene policy set up by the company.	
• A training timetable shall be set up for the reference person (Head of Application of Food Safety Regulations, HAFSR).	
• Training shall be programmed, evaluated and recorded.	
• Staff in the production areas shall be trained and informed about general hygiene concept, good manufacturing practices and hygiene policy set up by the company.	
• The company will carry out specific training courses for specific personnel whose activities require this.	
• A training timetable shall be set up for training of specific personnel.	
Good hygiene practices	
• All members of staff who enter any production area must wash or disinfect their hands.	
• No food or drinks can be brought into the production areas.	
• Water dispensers and/or bottles shall be in their designated places.	
• Plant staff and staff in charge of handling the final product shall wear appropriate protective clothing in order to avoid risks of contamination (clean protective clothing for exclusive use, and a protective head cover which completely covers the hair).	

Below are some examples of the types of documents needed to fulfil this requirement.

READING OF HYGIENE POLICY DOCUMENT BY STAFF MEMBERS RECORD			
Date	**Full name of the employee**	**Position**	**Signature**

Table 1: Example template of a reading of the hygiene policy document by staff members' record.

READING OF HYGIENE RULES DOCUMENT BY STAFF MEMBERS' RECORD			
Date	**Full name of the employee**	**Position**	**Signature**

Table 2: Example template of a reading of the hygiene rules document by staff members' record.

TRAINING PLAN			
WHAT	**FOR WHOM**	**WHEN**	**HOW**
Initial training: Staff hygiene rules	Plant staff	On joining the company	Internal or external training
Training course on the application of the requirements of guidance document	Plant staff	During the first year of work	
Specific training and training related to good manufacturing practices, applicable legislation, quality and hygiene.	Specific personnel and person in charge (HAFSR)	On joining the company or taking up the position, and as on-going training plan	

Table 3. Aspects which the hygiene training plan must encompass, adaptable according to risk group.

TRAINING ACTIVITY ATTENDANCE AND EVALUATION RECORD	
NAME OF TRAINING ACTIVITY:	
DATE OF TRAINING:	
NUMBER OF HOURS:	
CONTENTS:	
ORGANIZING COMPANY:	
FULL NAME OF EMPLOYEE:	**Signature**
POSITION:	
EVALUATION	
Compliance with objectives:	
Applicability to work position:	
Teacher evaluation:	
Methodology:	
Facilities, resources, timetables, etc.:	
Comments/Observations:	

Table 4. Example template of a training activity attendance and evaluation record.

A.4. GENERAL HYGIENE CONDITIONS

The requirements contained in this section shall establish the minimum measures that a food contact plastic materials and articles converter must take into account regarding facilities and equipment, water control, pest control and waste management.

A.4.1. FACILITIES AND EQUIPMENT HYGIENE

The hygiene measures concerning the facilities and equipment is shown below. These requirements must be taken into account for all new facilities. Already built facilities must strive to adapt to the measures.

Companies manufacturing materials and articles for both food contact and non-food contact use, must either physically separate the production area for food contact applications or implement hygiene measures in the whole production plant.

Requirement	Group
• All the facilities shall have an appropriate level of hygiene and cleanliness.	
• There must be a sufficient number of toilet facilities. These must have hot and cold water, and soap or cleaning products, as well as drying systems.	
• The production areas must have sufficient lighting to allow good production practices.	
• Equipment installation must reduce to a minimum the risk of contamination as well as allow for the cleaning of the equipment and its surrounding area.	
• Storage areas must have capacity to store separately raw material from finished products in a correct way.	
• Companies must have a purging and cleaning procedure between manufacturing of different types of articles or materials.	
• In case of having machinery intended to plastic manufacturing for both food contact and non-food contact uses, companies must have a purging and cleaning procedure between the manufacturing of food contact and non-food contact articles.	
• If cleaning is carried out by an external company, it must be controlled by the designated person in charge. There should be a cleaning record.	
• There must be changing facilities for the production staff. The cchanging facilities must be built from materials which can be easily cleaned.	

Requirement	Group
• There must be a cleaning plan for moulds, nozzles and dies. Cleaning will consist of a purging step after each change of material. In the case of moulds, it will be necessary to clean all the surfaces of the cavities and the parting lines in order to eliminate any residue of oil and/or anticorrosive element used in its maintenance.	
• Machines, equipment and surfaces in contact with food packaging must be cleaned and disinfected at convenient frequency to avoid contamination.	
• Access doors will be in good condition, in order to comply with their role of physical separation between areas and prevent the entry of non-desirable elements which may contaminate the products being manufactured.	
• Lighting must be protected against the possibility of breakage and physical contamination of the finished product.	
• Reusable containers in contact with final products shall be easy to clean and, if necessary, simple to disinfect.	
• Products for cleaning and disinfection must be stored in a separate cupboard away from other chemical products, as well as away from production or handling areas of food contact articles.	
• Design of facilities shall allow appropriate cleaning and disinfection, avoid the accumulation of dirt and facilitate pest control.	
• Specific areas shall be set aside for eating and drinking. These areas must be kept in hygienic condition and must be physically separated from production areas.	
• There must be sufficient hand-washing facilities or disinfection sites at the entrances of production areas.	
• Internal transport equipment must be adequately cleaned to allow for hygienic transportation of raw material and manufactured articles.	
• Perimeters, warehouses and production areas must be clean and well maintained.	
• Ceilings must be built to minimise the accumulation of dirt, and reduce condensation and formation of undesirable mould.	
• Floors and walls must be kept in good condition, and shall be easy to clean and disinfect.	
• Adequate means of ventilation must be available, avoiding air currents passing from contaminated areas into clean areas.	

Requirement	Group
• All facilities shall have an appropriate level of hygiene and cleanliness. • Storage areas shall have sufficient capacity to correctly store the finished product. • Storage areas must have sufficient lighting.	Storage and distribution companies and importers
When supplying group 1 and 2 products	
• Lighting must be protected against the possibility of breakage and physical contamination of the finished product.	Storage and distribution companies and importers
• Access doors will be in good condition, in order to comply with their role of physical separation between areas and prevent the entry of non-desirable elements which may contaminate the products being manufactured.	Storage and distribution companies and importers

Below are examples of necessary documents to meet this requirement.

CLEANING PLAN			
CLEANING PLAN FACILITY	PERSON IN CHARGE	FREQUENCY	ACTION
Indicate area and equipment **Example:** Raw material warehouse	Person responsible for doing the task **Example:** Cleaning operator	Frequency **Example:** Fortnightly	Task to be done, including key aspects such as products to be used **Example:** Tidy up the raw materials Remove any element which could lead to dirt and contamination Cleaning of walk ways General inspection of raw material packaging

Table 5. Aspects which the Cleaning Plan must encompass, adaptable according to risk group.

CLEANING RECORD			
Date	**Area**	**Person in charge**	**Observations**

Table 6. Example of a cleaning record.

PURGING RECORD					
Date	**Machine**	**Used material**	**Kg**	**Person in charge**	**Observations**

Table 7. Example of a purging record.

A.4.2. WATER CONTROL

The company must control water supply sources and guarantee that water is fit for human consumption.

These measures are only applicable to those processes where the water comes into contact with the finished plastic articles, and where there is no post-cleansing process.

These measures are not applicable to storage and distribution companies and import companies which do not carry out manufacturing or handling processes.

Requirement	Group
The company shall have an adequate supply of potable water in accordance with current legislation. • If water comes from public water supply, this can be proven by showing the last water bill. • If water does not come from public water supply, the company must prove the water is potable by means of water analysis in accordance with current legislation.	
If the company has non-potable water supply systems: • The water can be employed for uses where it does not come into contact with the finished product. • This water shall be clearly identified and piped independently from the potable water supply, in such a way that there is no possibility of this water crossing into or flowing back into the potable water supply.	
Water recirculation systems: • A purging plan must be set up for its use in machinery. • If water comes into contact with finished products, this water must be potable and meet the requirements set out in table 8.	

ACTIVITY	TYPE OF SUPPLY	SELF CONTROL	
		Verification of the method of disinfection	
		Parameters to be verified	Frequency
Converter of plastic materials	Public water supply without intermediate deposit	N/A	
	Public water supply with intermediate deposit	Residual free chlorine for chlorine and its derivatives	Quarterly
	Own supply	Residual combined chlorine for chloramination	Monthly

Table 8. Frequency and control diagram of the health parameters of the water.

A.4.3. MAINTENANCE

Requirement	Group
• The company's preventative maintenance plan must take into account all aspects which minimize the possibility of contamination coming from the machinery being use.	
• In situations where calibration deficiencies could suppose a food safety risk, there must be a calibration plan for the measuring equipments that are critical for product contamination.	
• On finishing maintenance tasks, the machinery and equipment which has undergone maintenance must be left clean and free from any danger of contamination.	
• On finishing maintenance tasks, all products and materials used are to be removed if they suppose a contamination risk for the finished product.	
• Maintenance workers shall comply with the company's hygiene requirements even if they belong to an externally contracted service company. In situations where an external company is contracted, the external company must be informed about hygiene rules. The external company must read and sign the rules before entering the production area.	
• Processes which use compressed air in contact with plastic materials and articles shall include a specific section in the maintenance plan in order to ensure the quality of the air and filters used.	
• Tools and cleaning equipment, such as brushes, scourers, cleaning cloths, high pressure machinery, etc., must be kept clean and in good condition.	
• Handling instruments, such as knives and blades, must be monitored and kept in good condition.	

These measures are not applicable to finished product storage and distribution companies and import companies which do not carry out manufacturing or handling processes.

Below are examples of necessary documents to meet this requirement.

MAINTENANCE PLAN			
EQUIPMENT	**PERSON IN CHARGE**	**FREQUENCY**	**ACTION**
Equipment No 1 **Example:** Check-up of compressed air filters	Personnel designated by the company, this could be an internal or external service **Example:** Maintenance personnel	Decided by the company **Example:** Monthly	Description of the task to be carried out **Example:** Check the condition, cleanliness and replacement

Table 9. Aspects that the maintenance plan must encompass, adaptable according to risk group.

MAINTENANCE RECORD			
DATE	**EQUIPMENT**	**PERSON IN CHARGE**	**OBSERVATIONS**

Table 10. Example of maintenance activity record.

CALIBRATION PLAN	
CODE:	**EQUIPMENT:**
PROCEDURE:	**PERSON IN CHARGE:**
FREQUENCY:	**REFERENCE MATERIAL:**
RANGE AND SCALE DIVISION:	**QUALITY:**

Table 11. Example of calibration plan.

CALIBRATION RECORD			
DATE	**NAME AND SIGNATURE**	**CERTIFICATE NUMBER**	**CONDITION**

Table 12. Example of calibration record.

A.4.4. PEST CONTROL

The company must have a pest control system based on continuous surveillance. Measures shall be applied depending on the problems found in observation, being also focused on determining possible causes.

These measures apply to all risk groups, including storage and distribution companies and importers who store the product.

	TYPE OF INFESTATION		
	Cockroaches	**Rodents**	**Flying Insects**
Type of trap	Indicate the appropriate type of trap		
Monitoring frequency	Monthly (May to October) and bimonthly (rest of the year)	Monthly	Monthly (May to October) and bimonthly (rest of the year)
Maximum limit before beginning treatment	>6	Presence and/ or signs	Visible presence
Person in charge of monitoring	Person in charge of surveillance or external company		
Treatment company	Registered company or in-house personnel authorized to carry out the treatment		
Corrective actions	Revision of preventative measures, and in situations where the maximum limits set have been exceeded, contact the company assigned to carry out the treatment		

Table 13. Pest control surveillance system.

A.4.5. WASTE CONTROL

Requirement	Group
• Waste containers, both inside and outside of production plant, must be identified and kept away from contamination risk areas for finished products or raw materials.	
• The containers must be suitable for the purpose and prevent any possible escape/ leakage of the waste materials.	
• Waste management must be performed in an appropriate way according to current legislation.	

These measures are not applicable to finished product storage and distribution companies and import companies which do not carry out manufacturing or handling processes.

B. SPECIFIC REQUIREMENTS AND QUALITY CONTROL SYSTEM

Applicable to all risk groups, storage and distribution companies and importers based on their activity

B.1. RAW MATERIAL

1. The company shall establish quality specifications for raw materials which shall be checked on arrival. Raw material shall be delivered along with its corresponding technical datasheet including information about selected critical quality parameters. Below are some examples:

    a. For plastic pellets, some of the usual control parameters are density, melt flow rate, viscosity, etc.

    b. For inks and adhesives, processing parameters such as, for example, drying and setting times, must be shown.

    c. For semi-finished products, critical parameters for subsequent manufacturing and/or handling processes must be requested.

2. With regard to food safety criteria, the raw material supplier shall:

    - Provide a declaration of compliance. This information could also be included in the technical datasheet.
    - Inform the company about any change in composition which might have a bearing on the fulfilment of current legislation.
    - Update the declaration of compliance as soon as new data or legislation appears, or if there are any modifications to current legislation, whenever these affect the raw material being supplied.

Information that the declaration of compliance and /or technical datasheet must contain with regard to compliance with food safety legislation, both for raw material and semi-finished products, is shown in Annex IV of Regulation 10/2011. The information that the declaration of compliance must include is also set out, in general terms, in Annex V of this Guide.

The drawing up of a declaration of compliance for inks, varnishes, adhesives and other raw materials for which at present there is no specific legislation at the European level must be based on proposals set down in Annex V in this guide.

3. Reception, packaging and requirements prior to storage of raw material.

    a. Suppliers must package products in such a way that the possibility of external contamination is minimized. This is extremely important for semi-finished products, especially if they are not going to undergo a subsequent thermal process.

    b. Delivered raw material shall be inspected, and a record shall be kept of this inspection whenever any defects are found. Raw material shall not be accepted if it is contaminated with parasites, has any physical contamination, the packaging is in poor condition, or if material is in a poor state of preservation, etc.

    c. The supplier must state the ideal storage conditions for the product (temperature, humidity and maximum storage time). This information can be included in the declaration of compliance or technical datasheet.

    d. Any information related to aspects which could affect food safety shall be given in the declaration of compliance or technical datasheet.

4. Correct labelling of raw material. Mandatory information shall be visible on external packaging or in attached documentation, and shall include the following fields:

   a. The words "for food contact" or "suitable for food contact", or the symbol for food contact approval (glass and fork).

   b. If necessary, special instructions to be observed for safe and appropriate use, and/or storage conditions, when these are believed to be critical (e.g. limited storage time or period of use, etc.).

   c. Name or trade name and, in either case, the address or registered office of supplier.

   d. Adequate labelling[1] or identification to ensure traceability of the material or article (batch number, date, etc.).

5. Documentation. As well as the above mentioned, the raw material and semi-finished product suppliers must provide the following documentation:

   a. Raw material or semi-finished product technical datasheet with quality criteria.

   b. Declaration of compliance of raw material.

   c. Storage conditions for the raw material which could be included in the technical datasheet and/ or declaration of compliance.

Recommendations for raw materials used in the manufacturing of plastic articles for which there are no specific legislative measures (adhesives, printing inks and varnishes, coatings, etc.).

At present there are substances or compounds which are used in the manufacturing of plastic materials and articles which still are not covered by any specific legislative measures such as those set out in Regulation 1935/2004. Some of these materials are adhesives, printing inks and varnishes/ coatings used in food packaging applications.

The following actions have been proposed:

1. As far as possible, certify the food contact suitability of these materials according to any currently existing legislation, or other international recognised rules and recommendations

If the materials are not approved for food contact by the above means:

2. Use substances which are included in any legislation for foodstuffs or food contact materials, or use substances with proven, scientific evidence concerning the absence of toxicological effects on human health.

3. Have a proven declaration stating that during the manufacturing process no carcinogenic, mutagenic or substance toxic to reproduction has been used; or demonstrate by means of analysis that migration is below general ingestion levels set out in current legislation (10 ppb).[2].

1 Labelling information shall be in clearly visible, legible and indelible characters. Instructions for use must be in a language that consumers can easily understand.

2 The European Chemical Agency (http://echa.europa.eu/) has published a list of substances deemed at present to be carcinogenic, mutagenic or toxic to reproduction. These lists are open and are updated regularly. On this website there is a warning system which allows information to be updated.

RAW MATERIAL CONTROL			
CONTROL	**RECORD**	**FREQUENCY**	**WHO**
Quality specification of raw material	Technical datasheet	When there has been a change in composition or properties of material	Head of Quality Department and/or HAFSR
Food contact approval of raw material	Declaration of compliance	Change of composition Modifications to legislation which affect the product	Head of Quality Department and/or HAFSR
State of raw material and labelling	Record of raw material control	On reception	Person in charge of warehouse

Table14. Example of a control plan for raw material.

B.2. STORAGE OF RAW MATERIAL

- When storing raw material some external protection to avoid physical contamination must be included. In the case of sacks or bags, these must completely covered by external packaging.
- If dust or other physical contaminants have accumulated on external packaging, this must be removed before bringing the raw material into the production areas. If external packaging cannot be removed, it must be cleaned before being brought into the production areas.
- Companies manufacturing both food contact and non-food contact articles must clearly separate raw material for food contact from raw material which is not intended for this use. When it is impossible to carry out a physical separation, both types of materials must be identified in such a way that warehouse operators can easily distinguish them.
- Raw material silos and conveyance systems must be clean and in good condition.
- As far as possible, companies manufacturing both food contact and non-food contact articles must separate the silos used for each purpose.
- In the extreme, but justified situation where silos are used for both food contact and non-food contact materials, a cleaning plan must be set up when changing between the different types of material.
- Storage of non-conforming raw material shall be in clearly marked designated areas.

B.3. CUSTOMER REQUIREMENTS

Converters and/or retailers can include customer requirements as a document attached to declaration of compliance.

The table below shows aspects to be taken into account concerning customer requirements:

CUSTOMER REQUIREMENTS	
REQUIREMENT	**CUSTOMER SIGNATURE**
Foodstuff to be packaged Specify the foodstuff or group of foodstuffs which are going to be packaged in a packaging material or container.	
Quality parameters Examples: thickness, colour, dimensions, thermal resistance, mechanical properties, etc.	
Packing conditions Any packing parameter which could be critical for the quality and food safety of final product.	
Post-packing treatments Any preservation treatment required by foodstuff, as well as how long for, and at what temperature it is going to be in contact with the container.	
Conservation conditions Specifications about how long the product can be stored within the container.	
Post-sale treatment If there are any conditions to fulfil for both the foodstuff and packaging before being consumed. For example: microwave, oven, freezing, etc.	
Special considerations Any consideration not covered in the previous sections which could have an influence on the quality and food safety parameters of the material or container.	

Table 15. Some aspects the customer requirement document must take into account:.

B.4. PROCESSING AND PRODUCTION QUALITY CONTROL SYSTEM

A technical datasheet including processing and production control parameters able to affect quality and food safety of food contact plastic materials or articles must be developed.

This specification must gather together processing parameters that may influence composition and final structure of materials (formulation, additivation, orientation, crystallinity, thickness, etc) and aspects able to affect food safety parameters, specifically migration and organoleptic properties.

With regard to the process parameters:

- For each type of manufactured container or article, processing parameters should be established, as well as allowable tolerance to ensure that the requirements of the finished product are met.
- These processing parameters must be monitored for each production operation.
- Records of safety parameter monitoring must be available. Corrective measures must be envisaged for cases in which there are any deviations from established parameters.

Annex III sets out a selection of the most important parameters plastic converters must take into account, depending on each specific manufacturing process.

For processes not covered in Annex III, the company must define their processing control parameters in accordance with the general framework set out in this section.

Companies which simultaneously carry out several manufacturing processes must take into account the parameters established in each of them.

PROCESS QUALITY CONTROL			
WHAT	**WHO**	**WHEN**	**HOW**
Process parameter to be controlled (specification and tolerance) **Example:** Thickness 50 microns (±3 microns)	Who carries out this control **Example:** Worker	Frequency **Example:** Continuous	Equipment, measuring technique, standard or method **Example:** Internal procedure

Table 16. Process quality control parameters.

B.5. FINISHED PRODUCT. VERIFICATION OF THE FULFILLMENT OF BOTH LEGAL AND QUALITY REQUIREMENTS

This section sets out requirements that a plastic material or finished article must meet in order to satisfy both quality parameters and legal requirements for food contact applications.

It has been divided into two sections: the first one which points out critical parameters for guaranteeing packaging quality; and the second one dealing with critical parameters for compliance with legal requirements for food contact articles.

Product quality parameters:

- Companies must establish quality parameters for finished products as well as their allowable tolerances.
- These parameters must be verified according to the company's quality plan.
- There must be laboratory reports or records in order to verify that parameter control has been performed.
- Companies must have corrective measures in situation where there are deviations from established parameters.

The above information shall be included in technical datasheets of finished products.

Annex IV includes the main quality parameters of some plastic articles, classified by different packaging manufacturing processes. Manufacturing processes listed in Annex IV are the same as those mentioned in the previous section.

For products not covered in Annex IV, the company must define their quality control parameters in accordance with the general framework set out in this section.

Companies which simultaneously carry out several manufacturing processes must take into account the parameters established in each of them.

Food safety parameters:

- Companies must set food safety parameters for finished products as well as their allowable tolerances.
- These parameters must be periodically checked, selecting frequency according to obtained test results and associated risk of articles.
- There must be laboratory reports or records in order to verify that parameter control has been performed, as well as corrective measures if there are deviations from the parameters established.

Companies shall issue a written declaration of compliance for their final product based on these supporting documents.

With regard to food safety controls, required verifications include:

I) Overall migration testing according to current regulations.

This testing will be performed taking into account the real conditions of use of the food contact material or article. The declaration of compliance shall include fields mentioned in Annex V of this document.

The number of overall migration tests to be carried out can be reduced if tested material or articles are more restrictive, so test results for them can cover the ones for other less restrictive materials or articles. This must be proven through current scientific evidence.

II) Specific migration testing according to current regulations or internal procedures.

For substances included in the Union list lacking a reference analytical testing method, specific migration according to internal laboratory procedures is allowed to demonstrate compliance. For substances with no adequate analytical method available, the company must provide documentation which states that the absolute lack of analytical methodology. For these substances the availability of a methodology must be checked annually.

Specific migration testing can be screened in the following cases:

1. For non-volatile substances, if overall migration levels are below the specific migration limit set in Regulation 10/2011 for this substance. This exception cannot be applied to volatile substances, as overall migration testing does not take these substances into account.
2. For additives, even when assuming complete migration of additive content in the material or article, the obtained value does not exceed the specific migration limit for this additive.
3. When residual content of a substance present in the material or article, even assuming complete migration, does not exceed the specific migration limit.

The number of specific migration tests to be carried out can be reduced if tested material or articles are more restrictive, so test results for them can cover the ones for other less restrictive materials or articles. This must be proven through current scientific evidence.

Compliance with specific migration limits can be calculated based on mathematical modelling on condition that they are acknowledged by the European Commission.

III) Modification of the organoleptic characteristics.

Companies must demonstrate that food contact materials or articles do not cause organoleptic changes to packaged food. This shall be done by means of:

1. By using raw materials that are certified as inert from an organoleptic point of view. Converter's prior knowledge concerning raw materials can be also considered.
2. By carrying out testing on the finished product, this could be a suitable sensory analysis or any other quality criteria or indirect measure, in order to guarantee the absence of organoleptic effects in food.

FINISHED PRODUCT QUALITY CONTROL			
WHAT	**WHO**	**WHEN**	**HOW**
Property being checked **Example:** Tensile test	Who is performing the test **Example:** Quality technician	Frequency of testing **Example:** All batches	Equipment, measuring technique, standard or method **Example:** ISO standard XXXXX

Table 17. Quality control parameters of finished product.

FOOD SAFETY CONTROL			
WHAT	**WHO**	**WHEN**	**HOW**
Property being checked **Example:** Overall migration	Who is performing the test **Example:** External laboratory	Frequency of testing **Example:** Every x years	Equipment, measuring technique, standard or method **Example:** ISO standard XXXXX

Table 18. Food safety parameters of finished product.

B.6. STORAGE OF FINISHED PRODUCTS

Finished products must be stored in suitable conditions.

- Finished products shall not be stored in external areas.[3]
- Finished product shall not come into contact with the ground. If this is unavoidable, a defined area shall be prepared and protective measures shall be put in place to avoid direct contact.
- Packaging of final products shall be carried out within the production area in order to minimize contamination due to transport of products.
- Finished product must be appropriately packaged in order to avoid external physical contamination.
- Packaging used to contain finished products must be manufactured with food contact materials.
- Pallets and other wooden packaging must be in good condition to avoid contamination.
- Refused finished product may be stored in external areas, but only in clearly identified, designed areas.
- Companies manufacturing both food contact and non-food contact articles must clearly separate final products according to their intended use. When it is impossible to carry out a physical separation, both types of products must be identified in such a way that warehouse operators can easily distinguish them.

3 For companies in Group 3, for example manufacturers of containers intended for agriculture use (baskets or fruit boxes), pallets and other similar products duly justified, this point can be omitted.

B.7. TRACEABILITY AND RECALL OF NON-CONFORMING PRODUCTS

According to Article 17 of Regulation 1935/2004, companies shall have in place, document and maintain traceability systems with the following considerations:

- The traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.
- With regard to technological feasibility, business operators shall have in place systems and procedures to allow identification of the businesses from which and to which materials or articles and, where appropriate, substances or products covered by Regulation 2023/2006 and its implementing measures used in their manufacture are supplied.
- The materials and articles which are placed on the market in the European Community shall be identifiable by an appropriate system which allows their traceability by means of labelling or relevant documentation or information.
- Traceability system effectiveness shall be demonstrated by internal audits or traceability exercises.
- The company shall carry out periodically repeated traceability exercises, and their effectiveness shall be recorded.
- Companies in groups 1 and 2: quarterly.
- Companies in group 3, storage and distribution companies and importers: annually.

When a claim is received, or any suspicion arouses about product food safety or, in the worst case, a health alert is declared, a product recall procedure must be applied (see next page):

PRODUCT RECALL EXERCISE		
Random selection of BATCH: XXXX/YZ (date):		
Description of product:		
Customers supplied + STOCK in warehouse		
Name:		
Identification of starting raw materials		
Type	Supplier	Batch

Table 19: Example of record for product recall exercise.

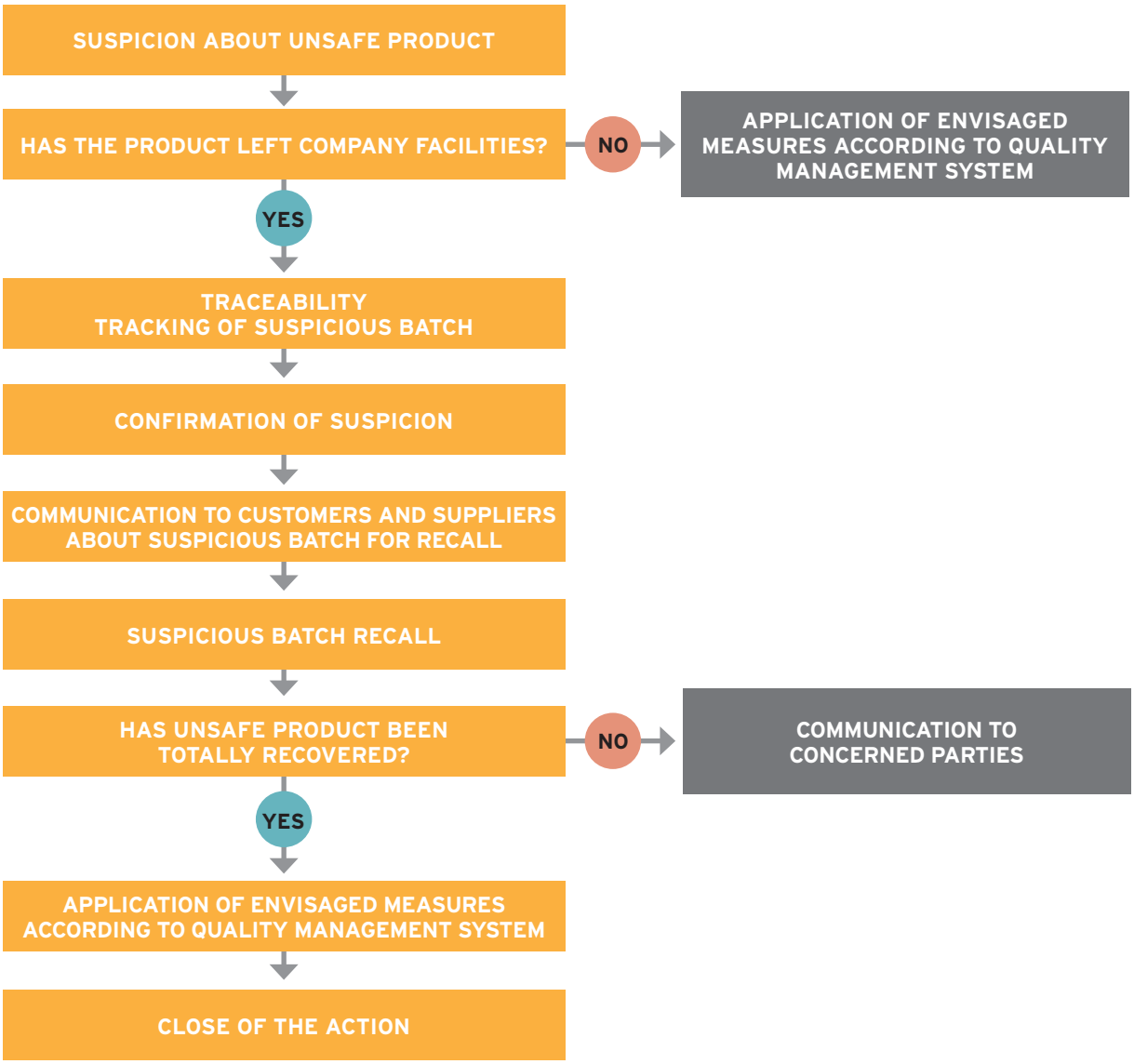


Figure 4. Non-conforming product recall procedure.

COMMUNICATION ABOUT MARKET RECALL			
Date of communication:		**Concerned company:**	
Name or reference of product to be recalled			
Batch	**Quantity**	**Date of delivery**	**Form**
Reason for recall and instructions to follow:			

Table 20: Example of record for product recall communication.

B.8. LABELLING

Materials and articles which are not yet in contact with food when placed in the market, but are intended to come into contact with food in the future, must be labelled according to Article 15 of Regulation 1935/2004:

- The words 'for food contact', or a specific indication as to their use, or the 'glass and fork' symbol (Figure 5). This information shall not, however, be obligatory for any articles which, because of their characteristics, are clearly intended to come into contact with food.
- If necessary, special instructions to be observed for safe and appropriate use.
- The name or trade name and, in either case, the address or registered office of the manufacturer, processor, or seller responsible for placing the product in the market established within the European Community.
- Adequate labelling or identification to ensure traceability of the material or article. Each sale unit shall be labelled or identified.

In the case of active materials and articles, they will comply with Regulation 450/2009. Some additional requirements on labelling for these materials and articles are the following:

- Active and intelligent materials and articles shall be adequately labelled to indicate that the materials or articles are active and/or intelligent.
- To allow identification by the consumer of non-edible parts, active and intelligent materials and articles or parts thereof shall be labelled, whenever they are perceived as edible:
    - With the words 'DO NOT EAT'; and always where technically possible, with the symbol reproduced in Figure 6.

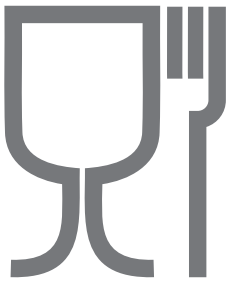


Figure 5: Food contact approval symbol

Figure 6: Do-not-eat symbol (Active substance)

C. CONTINUAL IMPROVEMENT

Company must maintain and document a continual improvement plan in order to demonstrate an increase in product quality and customer satisfaction. Senior management must be responsible for the application and revision of this plan.

Companies in Groups 1 and 2 must check the results of the plan at least once a year. Group 3 companies must carry out this review at least every two years.

In order to demonstrate continual improvement, companies must have some indicators based on:

- Claims/ complaints from customers.
- Incidents detected during the manufacturing process.
- Non-conforming products, pointing out which parameters are out-of-specification.
- An evaluation of customer satisfaction about received product.
- Official test control communications.
- Official test control results.

Given all this, a scheme for continual improvement plan would be the following:

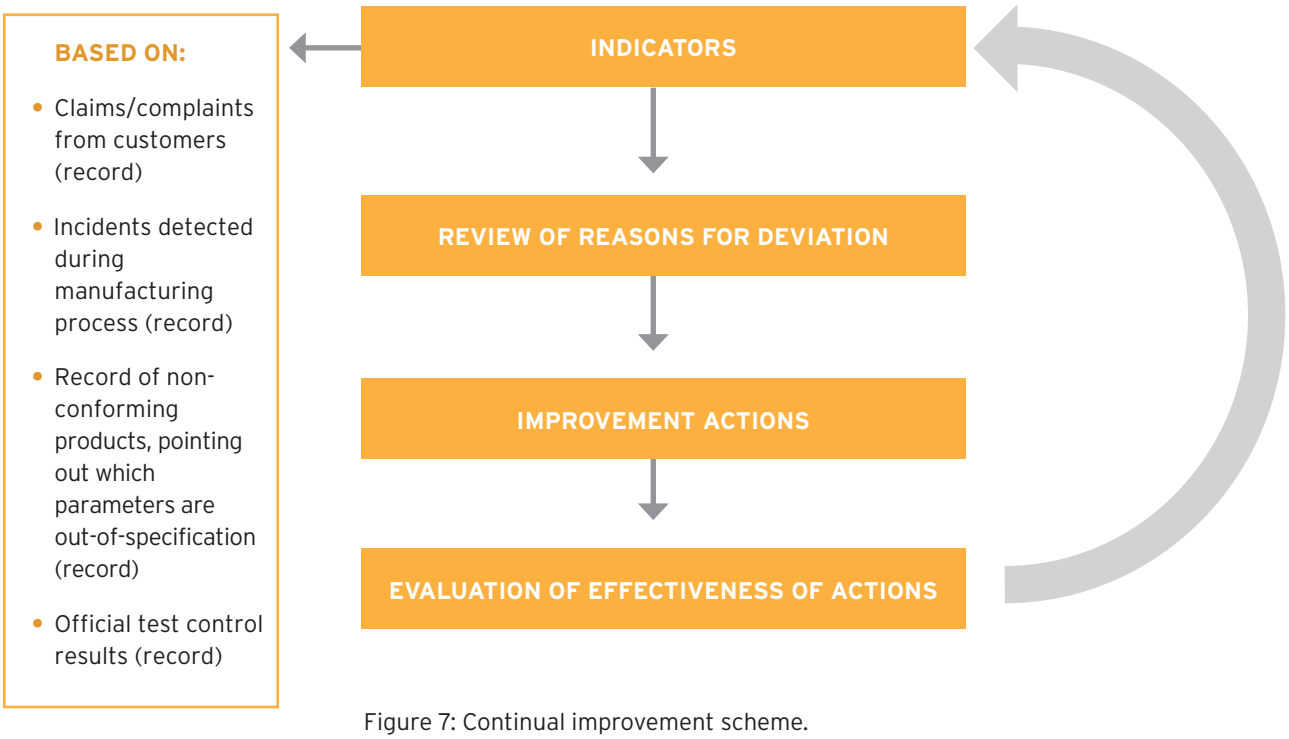


Figure 7: Continual improvement scheme.

Below are some examples of records needed within a continual improvement plan.

CUSTOMER CLAIM OR COMPLAINT RECORD			
Recorded by:		**Claim/complaint No:**	
Customer (Company):		**Contact person:** **E-mail:** **Telephone:**	
Product identification: **Order number:** **Description:**			
Subject matter of the claim:			
Customer proposal:			
Non-compensated complaint ☐	**Repeating of work** ☐	**Discounts** ☐	**Full refunding** ☐
Others (specify):			
Decision:			

Table 21: Example of a claims/complaints record.

INCIDENT DURING MANUFACTURING RECORD
Recorded by:
Identification of the incident:
Description:
Reason of incident:
Proposal of person in charge:
Decision:

Table 22: Example of a manufacturing incidents record.

NON-CONFORMING PRODUCT RECORD
Recorded by:
Identification of the incident:
Description:
Reason of incident:
Proposal of person in charge:
Decision:

Table 23: Example of a non-conforming product record.

ANNEX I:

Example of documentation control procedure

OBJECTIVE

To assure that quality control documents are prepared, revised, approved, published, distributed and administered as set out in this procedure.

SCOPE

To apply this procedure to all documents which are covered by quality assurance system whether they are internally generated or from external sources.

DEVELOPMENT

FORMAT, IDENTIFICATION AND PRODUCTION OF DOCUMENTS

The company must consider how to identify the documents, in the chosen format.

APPROVAL AND ISSUANCE OF DOCUMENTS

The company must define how it is going to manage approval and issuance of documents.

CHANGES IN THE DOCUMENTS

The company must consider how to inform about changes in the documentation, so that staff affected by the change adapt to it once it comes into force.

EXTERNAL DOCUMENTS

The company must consider the control of external documents, as well as the revision of modifications which may occur and affect manufactured products quality.

RESPONSIBILITIES

Define responsibilities.

RECORDS

Generated records from this document.

DISTRIBUTION

In this section the company must define how to distribute documents within the company.

RECORDS GENERATED FROM THIS PROCEDURE

Nº OF MODIFIED PAGE	REASON FOR THE CHANGE	DATE	SIGNATURE

Table 24: Example of a revision record.

RECEPTION DATE OF DOCUMENT	NAME AND CODE NUMBER OF RECEIVED DOCUMENT	VERSION NUMBER OF RETURNED DOCUMENT	COPY No	SIGNATURE OF PERSON WHO RECEIVES AND RETURNS

Table 25: Example of a document acknowledgement.

CODE NUMBER OF DELIVERED DOCUMENT	DELIVERY DATE	ADDRESSEE	COPY No.	VERSION NUMBER OF DELIVERED DOCUMENT

Table 26: Example of a document distribution record.

ANNEX II:
Example of quality policy

The company states that one of its main objectives is working according to good hygiene and manufacturing practices, in order to guarantee the quality and food safety of their manufactured products.

In order to comply with this objective, the workers responsibilities are defined as:

- To assume personal hygienic practices at all times .
- To apply hygiene rules and work practices defined by the company in order to eliminate any health risk from the manufactured products.
- To know and apply recommendations provided by the company with regard to safety and hygiene.
- To properly use personal and collective protective equipment, maintaining it in good condition.
- Strive to maintain order and cleanliness as a basic condition for all matters related to safety.
- To warn the supervisor of any damage or fault that may be dangerous and which may put product hygiene at risk.

ANNEX III:

Examples of some processing parameters to be controlled in the different manufacturing processes of containers

The manufacturing processes considered are the following ones:

- Blown Film Extrusion and co-extrusion: Manufacturing of monolayer or multilayer films
- Cast film extrusion and co-extrusion: Manufacturing of monolayer and multilayer films and sheets.
- Extrusion and co-extrusion blow moulding: Manufacturing of bottles and hollow objects, e.g. containers and jars, etc.
- Thermoforming: Manufacturing of trays
- Lamination and printing: Manufacturing of multilayer film
- Injection and co-injection moulding: Trays, closures, accessories, kitchenware, lunch boxes, etc.
- Blowing of preforms: Manufacturing of bottles and hollow objects, e.g. containers and jars, etc.
- Other secondary processes: cutting, winding and printing

Blown Film Extrusion and co-extrusion: Manufacturing of monolayer or multilayer films.

- Temperature profile
- Extrusion speed
- Melt temperature control
- Torque control
- Melt pressure control
- Blow-up ratio
- Stretch-up ratio
- Solidification line
- Blow height

Cast film extrusion and co-extrusion: Manufacturing of monolayer and multilayer films and sheets.

- Temperature profile
- Extrusion speed
- Melt temperature control
- Torque control
- Melt pressure control
- Rolls layout
- Rolls temperature
- Coefficient of friction between rolls
- Stretch-up ratio

Extrusion and co-extrusion blow moulding: Manufacturing of bottles and hollow objects, e.g. containers and jars.

- Temperature profile
- Extrusion speed
- Melt temperature control
- Torque control
- Melt pressure control
- Parison diameter adjustment and melt strength
- Parison length
- Mould closure speed
- Pinch-off edge
- Blown pressure
- Blown air flow
- Mould temperature
- Cooling time
- Mould open time and part ejection

Thermoforming: Manufacturing of trays.

- Types of thermoforming: vacuum, pressure, pre-blowing, with plug, combination of different types
- Mould type: male or female or multicavity
- Heating time
- Pre-blowing time
- Vacuum time
- Stretch-up ratio
- Cooling time
- Mould temperature

Lamination and printing: Manufacturing of multilayer films.

- Laminating speed
- Printing speed
- Technology application according to solvent or solvent-less adhesives.
- Applied adhesive measurement (g/m2)
- Drying parameters (temperature and air flow)
- Surface treatment conditions
- Adhesives curing time

Injection and co-injection moulding: Trays, closures, accessories, kitchen gadgets, lunch boxes, etc.

- Holding time
- Holding pressure
- Melt temperature
- Mould temperature
- Design and position of mould cooling channels

Blowing of preforms: Manufacturing of bottles and hollow objects, e.g. containers and jars.

- Blown pressure
- Preform temperature
- Preform grammage
- Blown moulding temperature

Other secondary processes: cutting, winding and printing.

If companies involved in handling operations such as cutting, winding, manufacturing of bags, etc., have migration results of products to be handled, it is not necessary for them to repeat migration and organoleptic analysis, as handling processes do not affect the migration values.

If the above companies perform printing on materials, they must ensure the following:

- Printing inks must be applied to the non food-contact side of materials and articles.
- They should carry out comparative overall migration testing[4] on printed and non-printed films in order to determine the influence of inks on migration values.
- Residual solvent must be controlled.

All printing companies, regardless of risk group, must ensure:

- Printing inks must be applied to the non food-contact side of materials and articles.
- They should carry out migration testing only on printed products[6], in order to include ink contribution to migration values.
- Residual solvent must be controlled.[5]

4 This point must be adapted when specific legislation for printing inks is available.

5 The residual solvent test can be omitted if it can be guaranteed that the drying specifications established by the ink supplier are met. When the material is used before this safety period, the printing company must carry out analytical controls to verify that the sample meets a suitable specification.

6 In printing cases in which the same plastic article is used and only the composition of inks varies, a comparative test between printed and non-printed products will be accepted, in order to determine the influence of inks on migration values. This point must be adapted when specific legislation for printing inks is available.

ANNEX IV:

Example of parameters to be controlled in order to verify quality and food safety characteristics of the manufactured products

Blown Film Extrusion and co-extrusion: Manufacturing of monolayer or multilayer films.

Quality parameters for the product.

- Material/materials (structure)
- Total thickness
- Total width
- Grammage
- Number of layers and thickness ratio
- Physical, optical and mechanical properties
- Absence of visual defects (marks, lines, gels, etc.)

Food safety parameters.

- Overall migration
- Specific migration
- Use of raw materials that are certified to be inert from an organoleptic point of view. The converter's prior knowledge concerning the absence of organoleptic effects when using this raw material can also be acceptable. If this information is not available, the absence of organoleptic effects on food must be verified by means of a sensory analysis or other indirect determination.

Cast film extrusion and co-extrusion: Manufacturing of monolayer and multilayer films and sheets.

Quality parameters for the product.

- Material/materials (structure)
- Total thickness
- Total width
- Grammage
- Number of layers and thickness ratio
- Physical, optical and mechanical properties
- Absence of visual defects (marks, lines, gels, etc.)

Food safety parameters.

- Overall migration
- Specific migration
- The converter's prior knowledge concerning the absence of organoleptic effects when using this raw material can also be acceptable. If this information is not available, the absence of organoleptic effects on food must be verified by means of a sensory analysis or other indirect determination.

Extrusion and co-extrusion blow moulding: Manufacturing of bottles and hollow objects, e.g. containers and jars.

Quality parameters for the product.

- Material/materials (structure)
- Weight
- Dimensions
- Thickness distribution
- Hermeticity (pores and leaks)
- Number of layers and thickness ratio
- Absence of visual defects (marks, lines, gels, etc.)

Food safety parameters.

- Overall migration
- Specific migration
- Use of raw materials that are certified to be inert from an organoleptic point of view. The converter's prior knowledge concerning the absence of organoleptic effects when using this raw material can also be acceptable. If this information is not available, the absence of organoleptic effects on food must be verified by means of a sensory analysis or other indirect determination.

Thermoforming: Manufacturing of trays.

Quality parameters for the product.

- Material/materials (structure)
- Weight
- Dimensions
- Thickness distribution (minimum and maximum thickness)
- Number of layers and thickness ratio
- Physical, optical and mechanical properties

Food safety parameters.

- Overall migration
- Specific migration
- Use of raw materials that are certified to be inert from an organoleptic point of view. The converter's prior knowledge concerning the absence of organoleptic effects when using this raw material can also be acceptable. If this information is not available, the absence of organoleptic effects on food must be verified by means of a sensory analysis or other indirect determination

Lamination and printing: Manufacturing of multilayer film.

Quality parameters for the product.

- Materials
- Adhesives
- Inks
- Varnishes
- Number of layers and thickness ratio
- Total thickness
- Total width
- Peeling resistance (delamination)[7]
- Residual solvents

Food safety parameters.

- Overall migration
- Specific migration
- Verification of materials not posing organoleptic problems (Carrying out of sensory analysis or residual solvents)
- If isocyanate adhesives are used: Determination of primary aromatic amines

Injection and co-injection moulding: Trays, closures, accessories, kitchen ware, lunch boxes, etc.

Quality parameters for the product.

- Material/materials (multilayer)
- Melt flow index of materials
- Weight
- Dimensions (including neck dimensions for preforms)
- Depending on type of final product, the company may apply other specific controls on finished products

Food safety parameters.

- Overall migration
- Specific migration
- Use of raw materials that are certified to be inert from an organoleptic point of view. The converters prior knowledge concerning the absence of organoleptic effects when using this raw material can also be acceptable. If this information is not available, the absence of organoleptic effects on food must be verified by means of a sensory analysis or other indirect determination.
- For injection moulding manufacturing of PET preforms: Verification of materials not posing organoleptic problems (Carrying out of sensory analysis or acetaldehyde quantification).

7 Peeling resistance and residual solvents tests can be omitted if it can be guaranteed that the curing and drying specifications established by adhesive and ink suppliers are met. When the material is used before this safety period, companies must carry out analytical controls to verify that the sample meets a suitable specification.

Blowing of preforms: Manufacturing of bottles and hollow objects, e.g. containers and jars.

Quality parameters for the product.

- Material/materials (multilayer)
- Weight
- Dimensions (including height)
- Thickness distribution
- Number of layers and thickness ratio
- Absence of visual defects
- Depending on the type of final product, the company may apply other specific controls on finished products

Food safety parameters.

- Overall migration
- Specific migration
- Use of raw materials that are certified to be inert from an organoleptic point of view. The converters prior knowledge concerning the absence of organoleptic effects when using this raw material can also be acceptable. If this information is not available, the absence of organoleptic effects on food must be verified by means of a sensory analysis or other indirect determination.

Other secondary processes: cutting, winding and printing.

If companies involved in handling operations such as cutting, winding, manufacturing of bags, etc., have migration results of products to be handled, it is not necessary for them to repeat migration and organoleptic analysis, as handling processes do not affect the migration values.

If the above companies perform printing on materials, they must ensure the following:

- Printing inks must be applied to the non food-contact side of materials and articles.
- They should carry out comparative overall migration testing [8] on printed and non-printed films in order to determine the influence of inks on migration values.
- Residual solvent must be controlled.[9]

All printing companies, regardless of risk group, must ensure:

- Printing inks must be applied to the non food-contact side of materials and articles.
- They should carry out migration testing only on printed products [10], in order to include ink contribution to migration values.
- Residual solvent must be controlled.[9]

8 This point must be adapted when specific legislation for printing inks is available.

9 The residual solvent test can be omitted if it can be guaranteed that the drying specifications established by the ink supplier are met. When the material is used before this safety period, printing company must carry out analytical controls to verify that the sample meets a suitable specification.

10 In printing cases in which the same plastic article is used and only the composition of inks varies, a comparative test between printed and non-printed products will be accepted in order to determine the influence of inks on migration values. This point must be adapted when specific legislation for printing inks is available.

ANNEX V:
Declaration of compliance

After manufacturing the final articles according to the product technical datasheet, and performing the required food safety tests, companies must prepare a **declaration of compliance** for the manufactured product.

The **declaration of compliance** is a document compiling all legislation to be fulfilled by the article, as well as specifications for its appropriate use.

Annex IV of Regulation 10/2011 sets out the information which the **declaration of compliance** shall contain:

1) The identity and address of the business operator issuing the declaration of compliance;

2) the identity and address of the business operator which manufactures or imports the plastic materials or articles or products from intermediate stages of their manufacturing or the substances intended for the manufacturing of those materials and articles;

3) the identity of the materials, the articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials and articles;

4) date of the declaration;

5) confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet relevant requirements laid down in Regulation (EC) 10/2011 and Regulation (EC) No 1935/2004;

6) adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annexes I and II of Regulation (EC) 10/2011 to allow the downstream business operators to ensure compliance with those restrictions;

7) adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 2008/60/EC, 95/45/EC and 2008/84/EC to enable the user of these materials or articles to comply with the relevant EU provisions or, in their absence, with national provisions applicable to food;

8) adequate information relative to global and specific migration values. Specifications on the use of the material or article, such as:

   - type or types of food with which it is intended to be put in contact;
   - time and temperature of treatment and storage in contact with the food;
   - ratio of food contact surface area to volume used to establish the compliance of the material or article;

9) when a functional barrier is used in a multi-layer material or article, the confirmation that the material or article complies with the requirements of Regulation 10/2011.

The written declaration shall permit an easy identification of the materials, articles or products from intermediate stages of manufacture or substances for which it is issued. It shall be renewed when substantial changes in the composition or production occur that bring about changes in the migration from the materials or articles or when new scientific data becomes available.

The declaration shall also include requirements included in other legislation related to non-plastic materials, use of recycled materials, active and intelligent materials, inks, adhesives, etc.

ANNEX VI:
Model of a traceability procedure

OBJECTIVE

The objective of this procedure is to guarantee traceability by means of a system which allows the material to be identified all the way from since reception to the final product reaching the consumer.

SCOPE

This procedure will be applied to all materials and products intended to come into contact with food manufactured or distributed by the companies within the scope of this guide.

DEVELOPMENT

Definitions

Traceability: The ability to trace and follow a material or article throughout all the stages of production, processing and distribution.

Traceability can be represented by the following diagram:

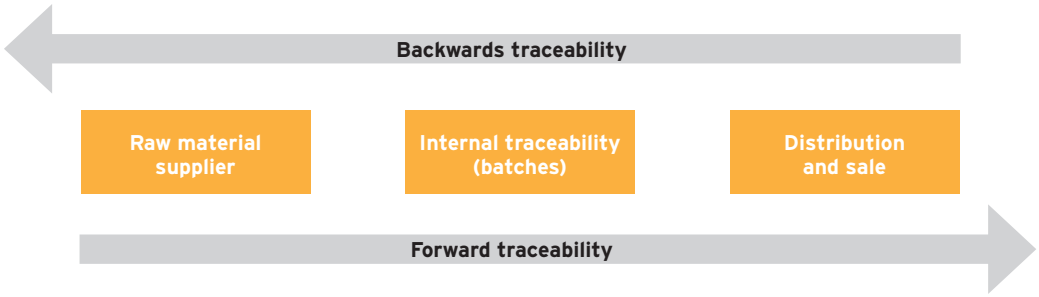


Figure 8: Traceability diagram.

Backwards traceability: Verification of the supplies arriving with the following information:

- What was exactly received and how much (name, batch number, quantity, etc.).
- Who were the products received from (name, address, information related to the establishment and products/ supplier).
- When it was received (reception date).

The purchase delivery note can substitute for the record if it includes all the above information.

Forward traceability: A record shall be made available with the required information to easily locate customers so that, if necessary, the product can be recalled if safety issues arise:

- Who the product is delivered to (information relating to the establishment which the merchandise is delivered to and the customer).
- What is delivered and how much (type of product, quantity, number of articles, etc.).
- When it is delivered (delivery date).

Internal traceability: When necessary the products entering and leaving the company will be linked, in order to obtain information concerning the process to establish a link with the final product.

Traceability

This document must guarantee that information related to details about the supplier of the product, the products supplied and delivery date can be provided immediately. This can be done by designed a coding system for the containers, or the packages that contain the containers and materials intended to come into contact with food.

Whenever necessary, all the remaining information must be made available to all members of staff within the chain and/ or the competent authorities as soon as possible.

A traceability exercise must be carried out (specify frequency) and its effectiveness must be registered.

RESPONSIBILITIES

Senior management is directly responsible for the implementation of this document.

RECORDS

Below are the records generated from the application of this procedure:

- Record of market recall for a product.
- Record of Traceability exercise.

ANNEX VII:
Decision tree to carry out testing

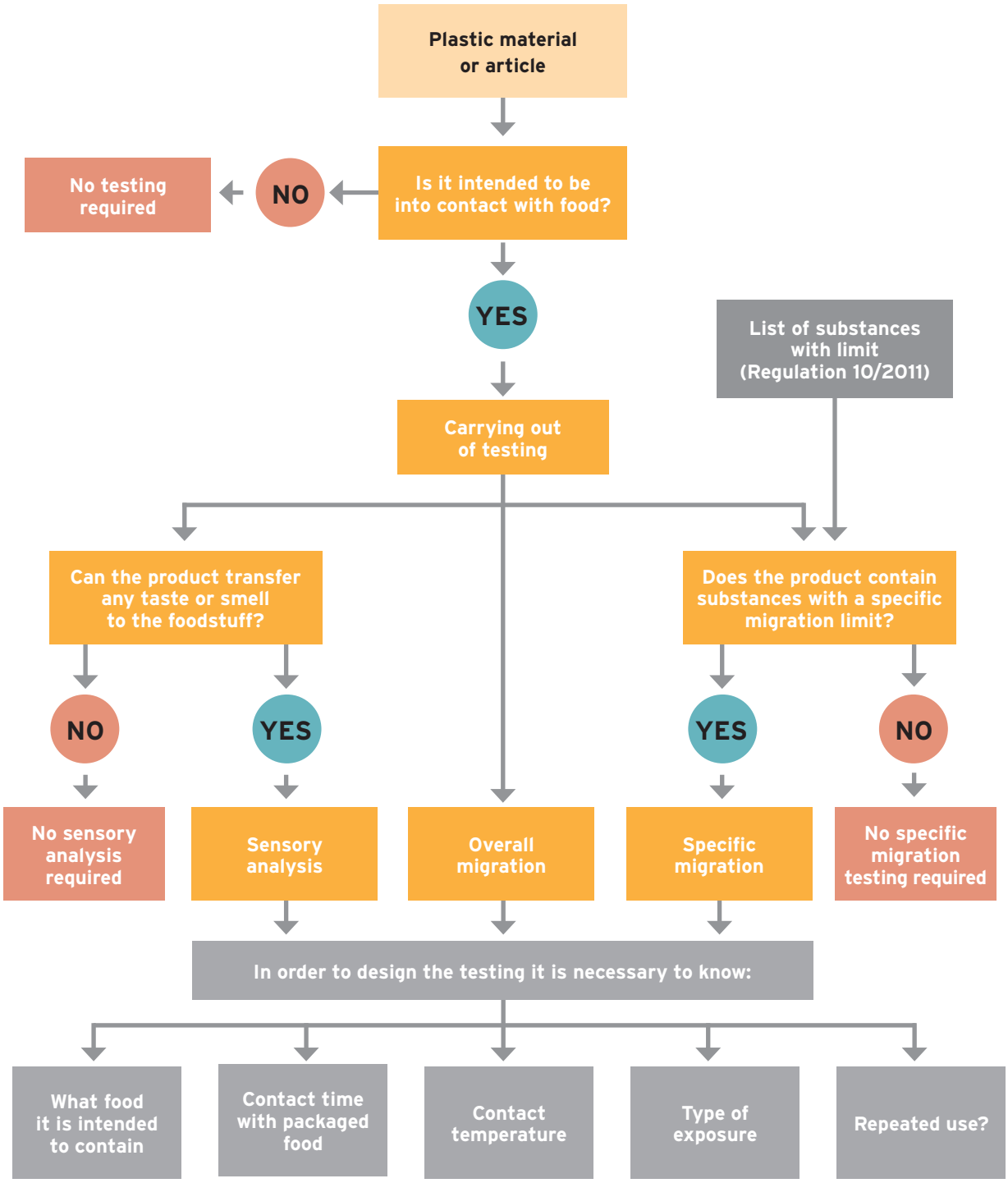


Figure 9: Decision tree to carry out testing.

9. Bibliography

In the development of this document, all the applicable legislation already mentioned in Section 5 of this guidance document has been reviewed. Moreover, the following relevant documents have also been consulted:

- Plastics Europe. **Guide for good manufacturing practices for plastic materials and articles intended to come into contact with foodstuffs**, 2008.
- FEDACOVA. **Guide for correct hygiene practices in cold and non-cold storage**, 2010.
- FLEXIBLE PACKAGING EUROPE, CITPA (2011) **Code for good manufacturing practices for flexible and fibre-based packaging for food.** [Online] http://www.flexpackeurope.org/upload/Documents/FPE_GMP_Code_6.0.pdf [Accessed 25 July 2011].
- British Retail Consortium (BRC). **BRC/IOP Global Standard for Packaging and Packaging Materials: Issue 4. TSO (The Stationery Office**), 2011.
- AESAN, **Guide for the application of a traceability system for food and agriculture companies**, 2004.

10. Useful links

www.avep.es

www.aimplas.es

www.obsevatorioplastico.com/envase

www.sp.san.gva.es

www.aesan.msc.es

www.efsa.europa.eu

Guidance on

Good Manufacturing Practices for food contact plastic materials and articles